



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,790	09/19/2001	Paul Laurence Cervi	13533-002001/F/USP81213	2047

26161 7590 12/22/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,790

Applicant(s)

CERVI, PAUL LAURENCE

Examiner

Brian Szmali

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-27, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 14, 16, 17, 19 and 21 is/are rejected.
- 7) ☒ Claim(s) 6, 12, 13, 15, 18 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Objections

1. Claim 1 is objected to because of the following informalities: In lines 8-9, "along the tube said tube to abrade" appears it should read as "along the tube to abrade".

Appropriate correction is required.

2. Claim 21 is objected to because of the following informalities: In lines 1-2, "the said needle" should read as either "the needle" or as "said needle". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 7-11, 14, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Doppeit.

Doppeit discloses a bone biopsy apparatus and further discloses a handle for inserting the instrument into the tissue; a single hollow tube for both cutting and receiving a tissue sample, coupled to the handle; the tube having (a) a bore defining a tissue-receiving space for the tissue sample, (b) a substantially rigid tip, and (c) an outer wall configured to contact the tissue, the outer wall being provided with an abrading formation extending in an axial direction along the tube to abrade the tissue; the tip of the tube to be laterally displaced within the bone marrow tissue to facilitate retrieval of the tissue sample; the

Art Unit: 3736

abrading formation comprises at least one slot cut into the outer wall, the slot having at least one sharp edge; two outer edges of the slot are defined by the intersection of the slot with the outer wall, and wherein both outer edges are sharp; the slot extends through the sampling tube between the outer wall and the bore; the abrading portion comprises a plurality of slots spaced circumferentially about the tube; the slot extends in an axial direction at least 1cm from the tip; the tube further comprises a sample detacher at the tip of the sampling tube tip wall to assist in detaching the base portion of the tissue sample from adjoining tissue; the sample detacher comprises a slot cut into the wall of the tip; the sample detacher slot extends through the wall of the tip; the sample detacher comprises a plurality of sample detacher slots spaced circumferentially spaced on the tip; a stop to prevent over-insertion of the tube into the tissue; the tube bore extends through the handle; inserting the sampling tip into the substance to be sampled to collect a sample within a bore; gyrating the sampling tip such that the substance is abraded to allow the sampling tip to be displaced laterally sufficiently to weaken a connection between the sample and the bulk of the substance; and withdrawing the sampling tip with the sample therein. See Column 4, lines 8-28; Column 5, lines 51-59; Column 6, lines 21-26; and Figure 8.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3736

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doppeit as applied to claim 1 above, and further in view of Baldrige.

Doppeit, as discussed above, discloses a bone biopsy instrument, but fails to disclose the handle being adapted for connection to a suction device to the bore.

Baldrige discloses a bone biopsy instrument and further discloses the handle being adapted for connection to a suction device to the bore. See Column 7, lines 64-68; and Column 8, lines 1-7.

Since both Doppeit and Baldrige disclose bone biopsy instruments, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the instrument of Doppeit to include the use of a suction source, as per the teachings of Baldrige, since it would provide a means to aspirate a sample at the biopsy site, thereby increasing the biopsy sample and decreasing the amount of time to acquire the sample.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doppeit as applied to claim 1 above, and further in view of Islam et al.

Doppeit, as discussed above, disclose a bone biopsy instrument, but fails to disclose the sampling tube having a sharpened, beveled tip.

Islam et al disclose a bone biopsy needle and further disclose the sampling tube having a sharpened, beveled tip. See Figure 2.

Since both Doppeit and Islam et al disclose bone biopsy instruments, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

substitute the sampling tube of Islam et al for the tube of Doppeit, since the sampling tube of Islam et al is another variation of a bone biopsy sampling tube.

Allowable Subject Matter

8. The indicated allowability of claim 21 is withdrawn in view of the newly discovered reference(s) to Doppeit. Rejections based on the newly cited reference(s) are above.
9. Claims 6, 12, 13, 15, 18 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. The following is a statement of reasons for the indication of allowable subject matter: Claims 22-27, 29 and 30 remain allowable per the reasons set forth in Paper No. 7.

Response to Arguments

11. Applicant's arguments, see Paper No. 8, filed October 24, 2003, with respect to the rejection(s) of claim(s) 1, 8, 16 and 17 under Fleming, III have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Doppeit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-

Art Unit: 3736

3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-2701. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

BS



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700